signs. If conditions persists or increases, discontinue use and consult veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended 52 FR 7833, Mar. 13, 1987]

§ 524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

(a) *Specifications.* Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram of gentamicin base and betamethasone valerate equivalent to 0.284 milligram of betamethasone.

(b) *Sponsor.* See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs in the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

(2) For the treatment of infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. One actuation of the sprayer delivers 0.7 milliliter of the spray. The drug should be administered with two spray actuations 2 to 4 times daily for 7 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 740, Jan. 7, 1985, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 10220, Mar. 6, 1997]

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

(a) *Specifications.* Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram (g) tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 051259 for use of 7.5- or 15-g tubes, 10-, or 25-g bottles.

(3) No. 059130 for use of 10-, 20-, or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill ointment twice daily into the ear canal. Therapy should continue for 7 consecutive days.

(i) From 7.5- or 15-g tubes, 10-, 12.5-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 38973, July 21, 1993, as amended at 63 FR 31932, June 11, 1998; 68 FR 42970, July 21, 2003; 70 FR 8291, Feb. 18, 2005]

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

(a) *Specifications.* Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsor.* See No. 000061 in § 510.6(c) of this chapter.

(c) *Conditions of use—Dogs*—(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 5- and 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 5- and 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

(2) *Indications for use.* For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P.*

aeruginosa], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 15370, Mar. 31, 2003]

§524.1140 Imidacloprid and ivermectin.

(a) *Specifications.* The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100 milligrams (mg) imidacloprid and 800 micrograms (µg) ivermectin.

(b) *Sponsor.* See No. 000859 in §510.600(c) of this chapter.

(c) *Conditions of Use in Dogs*—(1) *Amount.* The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 µg/lb (80 µg/kg) of ivermectin, topically once a month.

(2) *Indications for Use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 78685, Dec. 26, 2002]

§524.1193 Ivermectin pour-on.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams of ivermectin.

(b) *Sponsors.* See sponsors in §510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 051259, 051311, 055529, 058829, 059130, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

(c) *Related tolerances.* See §556.344 of this chapter.

(d) *Special considerations.* See §500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. surnabada, Oesophagostomum radiatum*; (adults) *Strongyloides papillosus, Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis, H. lineatum*; mites *Sarcoptes scabei* var. *bovis*; lice *Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenoptes capillatus*; and horn flies *Haematobia irritans*.

(ii) It controls infections and prevents reinfection with *O. ostertagi, O. radiatum, H. placei, T. axei, C. punctata,* and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *H. placei, C. oncophora,* and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) *Limitations.* Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

[55 FR 50551, Dec. 7, 1990, as amended at 62 FR 38908, July 21, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 44385, Aug. 19, 1998; 66 FR 13236, Mar. 5, 2001; 66 FR 63165, Dec. 5, 2001; 68 FR 3817, Jan. 27, 2003; 68 FR 4713, Jan. 30, 2003; 69 FR 501, Jan. 6, 2004; 69 FR 62181, Oct. 25, 2004]

§524.1195 Ivermectin otic suspension.

(a) *Specifications.* Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) *Sponsor.* See No. 065274 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) *Indications for use.* For the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness